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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,905	03/26/2001	Felix Hausch	B0032/7014	9507

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/817,905	HAUSCH ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 8, 2005 has been entered. rejection of claim 24 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-15, 23 and 25-34, are rejected under 35 U.S.C. 102(b) as being anticipated by Monforte et al (U.S. Patent 5,700,642).

Monforte et al (U.S. Patent 5,700,642) teaches a method for the analysis of a sample of genetic material for detailed sequence information contained in a large set of distinct sequences of the sample (the "target sequences") (see abstract), comprising the following steps:

(1) producing an amount of nucleic acid templates containing the target sequences by multiplexed amplification of the sample of genetic material (see column

22, lines 25-41 and column 27, lines 3-10, where Monforte et al (U.S. Patent 5,700,642) teaches detection of different PCR products),

(2) using a chip with spatially separated locations containing a photocleavable oligonucleotide probe for a different one of the target sequences to be investigated, the probes covalently bound to the chip surface (see column 24, lines 57-67, where Monforte et al (U.S. Patent 5,700,642) teaches the use of array of immobilized cleavable primers attached to a support)(for the new "different" language, see column 26, lines 1-12, where Monforte teaches the use of multiple different probes targeted to different sequences for detection of multiple different pathogens in a mixed population),

(3) modifying, in a single reaction vessel and by using the templates produced in step (1), all oligonucleotide probes on the chip synchronously in a template-dependent manner so that the information under investigation is transferred from the target sequences of the templates to the probes (see column 24, line 57 to column 25, line 3, where Monforte et al (U.S. Patent 5,700,642) teaches primer extension of the primers which transfers sequence information in a template dependent manner from the target to the probes),

(4) cleaving and mass spectrometrically measuring the spatially separated probes (see column 24, line 67, where Monforte et al (U.S. Patent 5,700,642) teaches cleavage and column 25, lines 2-3 where Monforte et al (U.S. Patent 5,700,642) refers back to column 23 which teaches MALDI-TOF mass spectrometry for detection),

where the probes are measured "one after another" (see column 24, line 66 to column 25, line 1, where Monforte states "the different sequence primers are

sequentially cleaved and the presence or absence of an extension product is determined"),

(5) extracting the detailed sequence information from the mass measurements of the probes (see column 23 where Monforte et al (U.S. Patent 5,700,642) teaches MALDI-TOF measurements to obtain sequence information).

With regard to claim 2, Monforte et al (U.S. Patent 5,700,642) teaches MALDI-TOF with laser desorption pulses (see column 23, lines 38-44).

With regard to claim 3, Monforte et al (U.S. Patent 5,700,642) teaches amplification in a single reaction vessel (on a single array) (see column 24, lines 57-67).

With regard to claims 4 and 5, Monforte et al (U.S. Patent 5,700,642) teaches purification and photolytic cleavage (see column 24, lines 57-67 and column 21, lines 38-39).

With regard to claim 6, Monforte et al (U.S. Patent 5,700,642) teaches photolytic cleavage and desorption (see column 23, lines 38-44).

With regard to claims 7-8, Monforte et al (U.S. Patent 5,700,642) teaches MALDI-TOF measurement of probes and photolytic cleavage (see column 23, lines 38-44).

With regard to claims 9-10, Monforte et al (U.S. Patent 5,700,642) teaches template dependent primer elongation including the use of ddNTPs (see column 20, lines 39-65).

With regard to claims 11-12, Monforte et al (U.S. Patent 5,700,642) teaches the use of ligation for extension (see column 4, lines 53-54).

With regard to claim 13, Monforte et al (U.S. Patent 5,700,642) determines the DNA sequence of the target (see column 20, lines 39-67).

With regard to claims 14-15, 31 and 32, Monforte et al (U.S. Patent 5,700,642) teaches labeling the DNA with dNTPaS (see column 21, line 61), with biotin (see column 19, lines 60-65) or with radioisotopes or fluorophores (see column 23, lines 15-18) as well as the photocleavable linker (see column 23, lines 15-18).

With regard to claim 23, Monforte et al (U.S. Patent 5,700,642) teaches the presence of a ribonucleotide (see column 4, line 20).

With regard to claims 25-26, Monforte et al (U.S. Patent 5,700,642) teaches application to the method of PCR with heat stable enzymes on the chip (see column 26, lines 60-67).

With regard to claims 27 and 30, Monforte et al (U.S. Patent 5,700,642) clearly teaches arrays with more than 10 probes (see column 24, lines 58-61, referencing the Southern and Fodor arrays with multiple probes).

With regard to claim 28, Monforte et al (U.S. Patent 5,700,642) teaches nitrobenzyl residues (see column 11, lines 44-45).

With regard to claim 29, Monforte et al (U.S. Patent 5,700,642) teaches linkers which provide spacing (see column 12, lines 1-67).

With regard to claims 33-34, Monforte et al (U.S. Patent 5,700,642) teaches solid phase synthesis on a suport (see column 10, lines 48-67 and column 24, lines 58-61, referencing the Fodor array methods).

4. Claims 1-19, 23 and 25-34, are rejected under 35 U.S.C. 102(b) as being anticipated by Monforte et al (U.S. Patent 5,830,655).

Monforte et al (U.S. Patent 5,830,655) teaches a method for the analysis of a sample of genetic material for detailed sequence information contained in a large set of distinct sequences of the sample (the "target sequences") (see abstract), comprising the following steps:

(1) producing an amount of nucleic acid templates containing the target sequences by multiplexed amplification of the sample of genetic material (see column 35, lines 17-36, where Monforte et al (U.S. Patent 5,830,655) teaches detection of different PCR products),

(2) using a chip with spatially separated locations containing a photocleavable oligonucleotide probe for a different one of the target sequences to be investigated, the probes covalently bound to the chip surface (see column 38, lines 42-55, where Monforte et al (U.S. Patent 5,830,655) teaches the use of array of immobilized cleavable primers attached to a support))(for the new "different" language, see column 39, lines 53-65, where Monforte teaches the use of multiple different probes targeted to different sequences for detection of multiple different pathogens in a mixed population),

(3) modifying, in a single reaction vessel and by using the templates produced in step (1), all oligonucleotide probes on the chip synchronously in a template-dependent manner so that the information under investigation is transferred from the target sequences of the templates to the probes (see column 38, lines 42-55, where Monforte

et al (U.S. Patent 5,830,655) teaches primer extension of the primers which transfers sequence information in a template dependent manner from the target to the probes),

(4) cleaving and mass spectrometrically measuring the spatially separated probes (see column 38, lines 50-55, where Monforte et al (U.S. Patent 5,830,655) teaches cleavage and where Monforte et al (U.S. Patent 5,830,655) refers back to column 37 which teaches MALDI-TOF mass spectrometry for detection),

where the probes are measured "one after another" (see column 38, lines 50-52, where Monforte states "the different sequence primers are sequentially cleaved and the presence or absence of an extension product is determined"), and

(5) extracting the detailed sequence information from the mass measurements of the probes (see column 37 where Monforte et al (U.S. Patent 5,830,655) teaches MALDI-TOF measurements to obtain sequence information).

With regard to claim 2, Monforte et al (U.S. Patent 5,830,655) teaches MALDI-TOF with laser desorption pulses (see column 37, lines 19-25).

With regard to claim 3, Monforte et al (U.S. Patent 5,830,655) teaches amplification in a single reaction vessel (on a single array) (see column 38, lines 42-55).

With regard to claims 4 and 5, Monforte et al (U.S. Patent 5,830,655) teaches purification and photolytic cleavage (see column 33, lines 14-21 and column 38, lines 42-55).

With regard to claim 6, Monforte et al (U.S. Patent 5,830,655) teaches photolytic cleavage and desorption (see column 38, lines 42-55).

With regard to claims 7-8, Monforte et al (U.S. Patent 5,830,655) teaches MALDI-TOF measurement of probes and photolytic cleavage (see column 37, lines 1-62).

With regard to claims 9-10, Monforte et al (U.S. Patent 5,830,655) teaches template dependent primer elongation including the use of ddNTPs (see column 31, line 40 to column 32, line 35).

With regard to claims 11-12, Monforte et al (U.S. Patent 5,830,655) teaches the use of ligation for extension (see column 6, line 43).

With regard to claim 13, Monforte et al (U.S. Patent 5,830,655) determines the DNA sequence of the target (see column 33, lines 5-67).

With regard to claims 14-15, 31 and 32, Monforte et al (U.S. Patent 5,830,655) teaches labeling the DNA with biotin (see column 30, lines 55-61) or with radioisotopes or fluorophores (see column 36, lines 63-67) as well as the photocleavable linker (see column 38, lines 42-55).

With regard to claims 16-17, Monforte et al (U.S. Patent 5,830,655) teaches endonucleolytic cleavage by restriction enzymes (see column 5).

With regard to claim 18, Monforte et al (U.S. Patent 5,830,655) teaches the use of BsmF1 which is methylation sensitive (see column 5, line 1).

With regard to claim 19, Monforte et al (U.S. Patent 5,830,655) teaches the use of RNAse (see column 24, lines 29-33).

With regard to claim 23, Monforte et al (U.S. Patent 5,830,655) teaches the presence of a ribonucleotide (see column 6, line 18, for example).

With regard to claims 25-26, Monforte et al (U.S. Patent 5,830,655) teaches application to the method of PCR with heat stable enzymes on the chip (see column 41, lines 11-21).

With regard to claims 27 and 30, Monforte et al (U.S. Patent 5,830,655) clearly teaches arrays with more than 10 probes (see column 38, lines 42-55, referencing the Southern and Fodor arrays with multiple probes).

With regard to claim 28, Monforte et al (U.S. Patent 5,830,655) teaches nitrobenzyl residues (see column 20, line 4).

With regard to claim 29, Monforte et al (U.S. Patent 5,830,655). teaches linkers which provide spacing (see columns 19 and 20).

With regard to claims 33-34, Monforte et al (U.S. Patent 5,830,655). teaches solid phase synthesis on a suport (see column 20, lines 31-42 and column 38, lines 42-55, referencing the Fodor array methods).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monforte et al (U.S. Patent 5,830,655) in view of Winger et al (U.S. Patent 6,251,600).

Monforte et al (U.S. Patent 5,830,655) teaches a method for the analysis of a sample of genetic material for detailed sequence information contained in a large set of distinct sequences of the sample (the "target sequences") (see abstract), comprising the following steps:

(1) producing an amount of nucleic acid templates containing the target sequences by multiplexed amplification of the sample of genetic material (see column 35, lines 17-36, where Monforte et al (U.S. Patent 5,830,655) teaches detection of different PCR products),

(2) using a chip with spatially separated locations containing a photocleavable oligonucleotide probe for a different one of the target sequences to be investigated, the probes covalently bound to the chip surface (see column 38, lines 42-55, where Monforte et al (U.S. Patent 5,830,655) teaches the use of array of immobilized cleavable primers attached to a support))(for the new "different" language, see column 39, lines 53-65, where Monforte teaches the use of multiple different probes targeted to different sequences for detection of multiple different pathogens in a mixed population),

(3) modifying, in a single reaction vessel and by using the templates produced in step (1), all oligonucleotide probes on the chip synchronously in a template-dependent manner so that the information under investigation is transferred from the target sequences of the templates to the probes (see column 38, lines 42-55, where Monforte et al (U.S. Patent 5,830,655) teaches primer extension of the primers which transfers sequence information in a template dependent manner from the target to the probes),

(4) cleaving and mass spectrometrically measuring the spatially separated probes (see column 38, lines 50-55, where Monforte et al (U.S. Patent 5,830,655) teaches cleavage and where Monforte et al (U.S. Patent 5,830,655) refers back to column 37 which teaches MALDI-TOF mass spectrometry for detection),

where the probes are measured "one after another" (see column 38, lines 50-52, where Monforte (U.S. Patent 5,830,655) states "the different sequence primers are sequentially cleaved and the presence or absence of an extension product is determined"), and

(5) extracting the detailed sequence information from the mass measurements of the probes (see column 37 where Monforte et al (U.S. Patent 5,830,655) teaches MALDI-TOF measurements to obtain sequence information).

With regard to claim 2, Monforte et al (U.S. Patent 5,830,655) teaches MALDI-TOF with laser desorption pulses (see column 37, lines 19-25).

With regard to claim 3, Monforte et al (U.S. Patent 5,830,655) teaches amplification in a single reaction vessel (on a single array) (see column 38, lines 42-55).

With regard to claims 4 and 5, Monforte et al (U.S. Patent 5,830,655) teaches purification and photolytic cleavage (see column 33, lines 14-21 and column 38, lines 42-55).

With regard to claim 6, Monforte et al (U.S. Patent 5,830,655) teaches photolytic cleavage and desorption (see column 38, lines 42-55).

With regard to claims 7-8, Monforte et al (U.S. Patent 5,830,655) teaches MALDI-TOF measurement of probes and photolytic cleavage (see column 37, lines 1-62).

With regard to claims 9-10, Monforte et al (U.S. Patent 5,830,655) teaches template dependent primer elongation including the use of ddNTPs (see column 31, line 40 to column 32, line 35).

With regard to claims 11-12, Monforte et al (U.S. Patent 5,830,655) teaches the use of ligation for extension (see column 6, line 43).

With regard to claim 13, Monforte et al (U.S. Patent 5,830,655) determines the DNA sequence of the target (see column 33, lines 5-67).

With regard to claims 14-15, 31 and 32, Monforte et al (U.S. Patent 5,830,655) teaches labeling the DNA with biotin (see column 30, lines 55-61) or with radioisotopes or fluorophores (see column 36, lines 63-67) as well as the photocleavable linker (see column 38, lines 42-55).

With regard to claims 16-17, Monforte et al (U.S. Patent 5,830,655) teaches endonucleolytic cleavage by restriction enzymes (see column 5).

With regard to claim 18, Monforte et al (U.S. Patent 5,830,655) teaches the use of BsmF1 which is methylation sensitive (see column 5, line 1).

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With regard to claim 23, Monforte et al (U.S. Patent 5,830,655) teaches the presence of a ribonucleotide (see column 6, line 18, for example).

With regard to claims 25-26, Monforte et al (U.S. Patent 5,830,655) teaches application to the method of PCR with heat stable enzymes on the chip (see column 41, lines 11-21).

With regard to claims 27 and 30, Monforte et al (U.S. Patent 5,830,655) clearly teaches arrays with more than 10 probes (see column 38, lines 42-55, referencing the Southern and Fodor arrays with multiple probes).

With regard to claim 28, Monforte et al (U.S. Patent 5,830,655) teaches nitrobenzyl residues (see column 20, line 4).

With regard to claim 29, Monforte et al (U.S. Patent 5,830,655). teaches linkers which provide spacing (see columns 19 and 20).

With regard to claims 33-34, Monforte et al (U.S. Patent 5,830,655). teaches solid phase synthesis on a suport (see column 20, lines 31-42 and column 38, lines 42-55, referencing the Fodor array methods).

Monforte, while teaching restriction endonuclease cleavage methods, and suggesting the use of RNAse based methods, as discussed above, does not specifically address RNAse H based mismatch detection methods.

Winger teaches the use of RNAse H to detect mismatches by probe release (see column 8, lines 10-22 and column 14).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the method of Winger to detect mismatches and release the probe since Winger teaches the use of RNAse H to release probes and since Monforte expressly teaches the use of other endonucleases to release probes, so that RNAse H is a prior art known equivalent for use in RNA-DNA hybrids to other restriction endonucleases. Further, Winger specifically motivates the use of RNAse H when noting "Preferred embodiments of the invention employ RNAse H and probes composed, at least in part, of RNA that is cleavable by RNAse H when it forms a duplex with DNA (see column 4, lines 48-50)." So Winger teaches that RNAse H can be used in a release method to release regions of DNA for detection to distinguish perfect matches from mismatches. As MPEP 2144.06 notes " Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982)." Here, RNAse H is such an equivalent with regard to the endonucleases taught by Monforte as shown by Winger.

Response to Arguments

8. Applicant's arguments filed March 8, 2005 have been fully considered but they are not persuasive.

Applicant first argues that the Monforte method is not used for mutation analysis of a plurality of target sequences. This is not correct, since Monforte expressly teaches the use of an array of modified primers (see column 24, lines 58-62 of Monforte (5,700,642) for example. Further, as noted in the rejection, column 26, lines 1-12 clearly discusses the use of different nucleic acid primers. The argument that the primers are not used for "mutation detection" is not relevant since there is no claim limitation which distinguishes the method of Monforte from the currently claimed method.

Applicant has now incorporated the limitation argued but not claimed previously, that the probes are measured "one after another". A review of the Monforte references finds that both Monforte patents include the same sentence regarding the analysis of the samples, specifically "the different sequence primers are sequentially cleaved and the presence or absence of an extension product is determined" (see column 38, lines 50-52, Monforte (U.S. Patent 5,830,655). This teaching of "sequential" cleavage and detection is a direct teaching of measurement of the probes "one after another". In fact, the Webster's II New riverside dictionary defines sequential as "forming or marked by a sequence" and defines "sequence" as "A following of one thing after another" (see page 1064 of dictionary). Therefore, the express ordinary definition of the teaching of Monforte, would be that the different sequence primers are cleaved one after another.

Applicant does argue that the Monforte (5,700,642) provides not teaching of an array of nucleic acids on a chip. This is simply incorrect. At column 24, lines 57-67, Monforte (5,700,642) expressly teaches that "an array of the immobilized, cleavable primers can be formulated (Fodor et al 1991; Southern et al 1992)." This teaching is a direct teaching of a chip. The Fodor and Southern references refer to the original two inventors of biochip technology and this is an express teaching of a chip.

Applicant's claim has removed the inconsistency with claim 6, but as noted above, either Monforte patent teaches the sequential cleavage of the probes.

Since the Monforte patents are maintained as 102 rejections, the combination with Winger is also maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637
5/10/05